DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-002

October 7, 2014

A & D Engineering, Inc.
Mr. Jerry Wang
Director of Engineering
1756 Automation Parkway
San Jose, CA 95131

Re: K141160
Trade/Device Name: A&D Medical UA-651Digital Blood Pressure Monitor
Regulatory Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II (Two)
Product Code: DXN
Dated: September 5, 2014
Received: September 8, 2014

Dear Mr. Wang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Melissa A. Torres -S

For Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K141160

Device Name: A&D Medical UA-651 Digital Blood Pressure Monitor

Indications For Use:

Measure blood pressure (systolic and diastolic) and pulse rate.

Prescription Use _____ AND/OR Over-The-Counter Use ___X____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Summary

This summary of 510(k) safety and effective information is being submitted in accordance with the requirement of SMDA and 21 CFR 807.92.

1. Date Prepared

Octorber 03, 2014

2. Submitter's Information

A&D Engineering, Inc.
Mr. Jerry Wang
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Tel: 408-518-5113
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3. Device Information

Proprietary Name:	A&D Medical UA-651Digital Blood Pressure Monitor
Common/Usual Name:	Blood Pressure Monitor
Classification name:	Non-invasive blood pressure measurement System 21 CFR 870.1130, Class II, 74DXN.

4. Predicate Devices

A&D Model UA-1000 Family Digital Blood Pressure Monitors with 510(k) number K111686
A&D Model UA-767PBT Digital Blood Pressure Monitor with 510(k) number K043217
Predicate devices are designed and manufactured by the same company and facilities as the modified devices UA-651.

5. Device Description – Technological and Operational Characteristics

UA-651 uses an inflatable cuff which is wrapped around the patient's upper arm. After the user pushes the "START" button, the cuff is inflated automatically by an internal pump of UA-651. The systolic and diastolic blood pressures are determined by oscillometric method. The deflation rate is controlled by the internal exhaust valve. There is a quick exhaust mechanism so that the cuff pressure can be completely released urgently. There is a maximum pressure safety setting at 300mmHg. UA-651 will not inflate the cuff higher than 300mmHg. UA-651 will turn on an irregular heartbeat indicator if an irregular heartbeat was detected during the measurement process. At the end of the measurement, the systolic and diastolic pressures with pulse rate are shown on the LCD and stored in the device memory. The cuff is also deflated automatically to 0 mmHg at the same time. The detail comparisons among devices are listed below. Main features of the UA-651 are listed below.

6. Intended Use & Indicator for Use

Indended use: The A&D Medical UA-651 family digital blood pressure monitor is intended for used by a person older than twelve (12) years to measure the systolic and diastolic blood pressure and pulse rate.

Indications for Use: Measure blood pressure (systolic and diastolic) and pulse rate.

The intended user and the indication for use of A&D Medial UA-651 as described in the labeling are the same as their predicated devices, UA-1000 family and UA-767PBT.

7. Summary of Substantial Equivalence

Modifications made from the predicate devices:

- Change the plastic molds so UA-651 has a different appearance
- Reduce memory size and remove AM / PM function
- Remove the following functions from UA-1000 family – Voice, Tricheck, and AM/PM measurement average.
- Remove the Bluetooth wireless communication from UA-767PBT.

Product Specification Comparison

Parameter	**Predicate Devices (UA-1000 family & UA-767PBT)**	**Modified Devices (UA-651)**
Power source	4 AA size batteries and AC adaptor as an option	No Change – the same
Battery Life	4 months with daily measurement	No change – the same
Measurement Method	Oscillometric Method	No change – the same
Measurement Range	BP : 20 to 280 mmHg Pulse : 30 to 200 pulse/min	No change – the same
Accuracy	BP : +/- 3mmHg or +/- 2% of measured value, whichever is greater Pulse : +/- 5 % (pulse)	No change – the same
Pressurization Source	Automatic internal pump	No change – the same
Cuff Deflation Method	UA-767PBT – Standard exhaust valve UA-1000 family – Constant speed electrical controlled exhaust valve (ECEV method)	No change – the same as UA-767PBT
Display Type	Liquid crystal display	No change – the same
Cuff Attachment Method	By plastic hose connected to monitor	No change – the same
IHB (Irregular	More than +/-25% to the mean	No change – the same

Heartbeats Detection)	interval of all pulse intervals	
Operating Environment	50^0F (10^0C) to 104^0F (40^0C) 30 %RH to 85% RH	No change – the same
Storage Environment	14^0F (-20^0C) to 140^0F (60^0C) 10 %RH to 95% RH	No change – the same
Pressure Indicator	UA-1000 family (Yes) under USA JUC VII guideline	No change – the same
Data Memory Size with Time & Date	90 memories for UA-1000 family 40 memories for UA-767PBT	Reduce to 30 memories
Pressure Sensor design	Static electricity capacity type	No change – the same
Dimensions in mm	UA-767PBT: 163.7 x 111 x 66.7 UA-1000 Family: 140 x 60 x 105	190 x 83 x 165
Weight	UA-1010–265g UA-1020–285g UA-1030T–300g without batteries	300g without batteries
Cuff Design	UA-767PBT – D-ring cuffs UA-1000 family – U-shape cuffs	No change – the same as UA-767PBT
Arm Size	UA-289 small cuff : 16 to 24 cm UA-290 medium cuff : 23 to 37 cm UA-291 large cuff : 31 to 45 cm	No change
Clock (Time/Date)	Yes for UA-1020 and UA-1030T	Removed
Talking	Yes – UA-1030T, No - others	Removed
AM/PM	Yes – UA-1020 & UA-1030T	Removed
Wireless Radio Connectivity	UA-1000 family (No), UA-767PBT (Yes)	Removed
Personal PC Analysis Software	UA-1000 family (No), UA-767PBT (Yes)	Removed

Key Features Comparison

Parameter	**Predicate Devices (UA-1000 family & UA-767PBT)**	**Modified Devices (UA-651)**
Field service	Not allowed	No Change – the same
Automatic zero at "START"	Yes	No Change – the same
Manual zero adjustment	Not allowed	No Change – the same
Calibration	Not allowed in the field	No Change – the same
Sterilization	Not needed	No Change – the same

Substantial Equivalence Conclusion:
UA-651 Digital blood pressure monitors have the following similarities to the predicate devices, UA-1000 family and UA-767PBT digital blood pressure monitors, which previously received the 510(k) clearance.

- Same intended use.
- Same oscillometric method to determine the blood pressure & pulse rate
- Same inflation method – automatic internal pump
- Same deflation method – standard exhaust valve
- Same materials, no new materials used
- Same manufacturing processes at the same facility

As a conclusion, the intended use of the modified device, UA-651 as described in its labeling, has not changed as a result of the modifications. The fundamental scientific technology of the modified device, UA-651, has not changed, either. There is no significant difference that affects the safety or effectiveness of the modified device as compared to the predicate devices.